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Randomized Clinical Trial

Intrarenal pressure with hand-pump or pressurized-bag irrigation: randomized clinical trial at retrograde intrarenal surgery

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Abstract

Background: The aim was to ascertain the impact of irrigation technique on human intrarenal pressure during retrograde intrarenal surgery.

Methods: A parallel randomized trial recruited patients across three hospital sites. Patients undergoing retrograde intrarenal surgery for renal stone treatment with an 11/13-Fr ureteral access sheath were allocated randomly to 100 mmHg pressurized-bag (PB) or manual hand-pump (HP) irrigation. The primary outcome was mean procedural intrarenal pressure. Secondary outcomes included maximum intrarenal pressure, variance, visualization, HP force of usage, procedure duration, stone clearance, and clinical outcomes. Live intrarenal pressure monitoring was performed using a COMET™II pressure guidewire, deployed cystoscopically to the renal pelvis. The operating team was blinded to the intrarenal pressure.

Results: Thirty-eight patients were randomized between July and November 2023 (trial closure). The final analysis included 34 patients (PB 16; HP 18). Compared with PB irrigation, HP irrigation resulted in significantly higher mean intrarenal pressure (mean(s.d.) 62.29(27.45) *versus* 38.16(16.84) mmHg; 95% c.i. for difference in means (MD) 7.97 to 40.29 mmHg; $P = 0.005$) and maximum intrarenal pressure (192.71(106.23) *versus* 68.04(24.16) mmHg; 95% c.i. for MD 70.76 to 178.59 mmHg; $P < 0.001$), along with greater variance in intrarenal pressure (log transformed) (6.23(1.59) *versus* 4.60(1.30); 95% c.i. for MD 0.62 to 2.66; $P = 0.001$). Surgeon satisfaction with procedural vision reported on a scale of 10 was higher with PB compared with HP irrigation (mean(s.d.) 8.75(0.58) *versus* 6.28(1.27); 95% c.i. for MD 1.79 to 3.16; $P < 0.001$). Subjective HP usage force did not correlate significantly with transmitted intrarenal pressure (Pearson $R = -0.15$, $P = 0.57$). One patient (HP arm) developed urosepsis.

Conclusion: Manual HP irrigation resulted in higher and more fluctuant intrarenal pressure trace (with inferior visual clarity) than 100-mmHg PB irrigation.

Registration number: osf.io/jmg2h (https://osf.io/).

Introduction

Intrarenal pressure (IRP) is a topic of major concern in endourology. Raised procedural IRP during retrograde intrarenal surgery (RIRS) has been associated with an increased risk of urosepsis, postoperative pain, and collecting system rupture, among other potential adverse events[1–3].

Observational work has shown that *in vivo* IRP during RIRS is highly variable, and frequently exceeds traditionally quoted thresholds of 30–40 mmHg[2,4,5]. An individual patient's IRP is dependent on the interplay of several variables. Conceivably, irrigation technique contributes significantly to IRP; however, the impact of irrigation settings is unknown. A wide variety of possible irrigation techniques exists, including gravity inflow from various heights, pressurized-bag (PB) irrigation, manual irrigation with a hand-pump (HP) or a foot-pump device and automated inflow[6,7]. A global practice survey[8] has suggested

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that the manual HP is the most favoured class of irrigation device internationally. However, there is some evidence suggesting a higher incidence of systemic inflammatory response syndrome (SIRS)/sepsis following RIRS with HP irrigation[9]. This has been hypothesized to occur via a mechanism of HP resulting in increased and irregular IRP values, predisposing to pyelovenous backflow and bacterial translocation[9]. Preliminary work by the authors' group suggested that HP irrigation may indeed lead to high and fluctuant IRP traces, but data were limited and heterogeneity in patient and operative variables impeded direct comparisons based on irrigation technique alone[2]. Therefore, the aim of the present study was to examine the impact of HP *versus* PB irrigation on IRP in an *in vivo* RCT.

Methods

Study design

This was a multicentre, parallel RCT. Ethical review board approval for IRP measurement was granted at each institution (21/42; RS22-045). The study was registered via the Open Science Framework before data analysis (osf.io/jmg2h); the full protocol is available upon request. Eligible patients consenting to participate were recruited to undergo *in vivo* IRP monitoring during RIRS, and randomized, in a 1 : 1 ratio, to either manual HP or 100-mmHg PB irrigation with placement of an 11/13-Fr ureteral access sheath. The study complied with the CONSORT reporting guideline for randomized trials[10].

Inclusion and exclusion criteria

Consenting adults (aged at least 18 years) undergoing RIRS with laser lithotripsy for the treatment of intrarenal urolithiasis, and in whom the surgeon intended to place a ureteral access sheath, were included. Patients with ureteric calculi, ureteric strictures or staghorn calculi were excluded.

Intervention and operative techniques

All procedures were carried out under general anaesthesia, with perioperative antibiotic prophylaxis with an aminoglycoside. A COMET™II pressure guidewire (Boston Scientific, Marlborough, MA, USA), designed for intracoronary and peripheral endovascular use, was used off label, with ethical review board approval, for IRP monitoring in this study. Rigid cystoscopy was performed, the bladder was emptied, and the COMET™II pressure guidewire was passed via the working channel of the cystoscope, into the ureteric orifice, to the renal pelvis. Baseline IRP was recorded for 60 s. A standard guidewire was deployed and an 11/13-Fr ureteral access sheath passed (46 cm in men and 36 cm in women), with the tip positioned at the pelviureteric junction and the position confirmed fluoroscopically. RIRS was undertaken with a single-use 9.5-Fr digital flexible ureteroscope (LithoVue™; Boston Scientific), with lithotripsy of calculi using a 270-µm holmium : yttrium–aluminium–garnet laser fibre. All procedures were performed by one of three consultant urologists with endourology fellowship training. Irrigation was undertaken with either a 1-litre bag of normal saline (0.9% sodium chloride) at 2-m hook height with 100 mmHg pressure applied via a pressure infusion bag (PB arm), or with manual HP irrigation using a commercially available syringe-based irrigation device operated by one of three urologists (HP arm), who were requested to use the HP with the least force and frequency required to adequately facilitate the procedure. The IRP trace during RIRS was transmitted to an AVVIGO™ Guidance System (Boston Scientific) and recorded by using a standardized technique. Live 'bookmarks' were placed on IRP traces and a written record was kept to denote corresponding changes in operative technique. The pressure wire was removed after completion of the procedure. A ureteral stent was placed, according to surgeon preferences, and routine postoperative care was conducted.

Outcome measures

The primary endpoint was the mean IRP experienced during the intraoperative phase. Secondary outcomes were the maximum peak IRP recorded across the operative phase, the variance in IRP, the operator-reported force of HP usage (HP arm) reported by the surgeon immediately upon completion of the procedure, operator-reported average visualization during the operation on a 10-point scale as reported upon procedure completion, procedure duration recorded in minutes from commencement to cessation of laser use, stone clearance rates, and postoperative complications. Stone-free status was determined based on endoscopic calyceal inspection at the end of the procedure, and an immediate postoperative X-ray of the kidney, ureter, and bladder.

Sample size calculation

Based on preliminary observations by the authors' group[2], a mean(s.d.) IRP of 40(20) mmHg was anticipated in the PB arm and 60 mmHg in the HP arm. With a 1 : 1 allocation ratio and two-sided significance, with α set at 0.05 and power at 80%, a required sample size of 32 (16 in each arm) was calculated. The aim was to recruit a minimum of 36 patients to allow for drop-outs.

Recruitment and randomization

Patients were offered enrolment in the trial across the three participating institutions and those wishing to participate were randomized by the sealed envelope method in a 1 : 1 ratio. Sequentially numbered tokens concealed within envelopes were prepared by the first author and distributed among centres. Patients were blinded to the allocation. Simple randomization without restriction was applied.

Blinding

By necessity, the operating team was informed of the irrigation method of choice. However, the operating surgeon and surgical assistant were blinded to the live IRP trace during the procedure. The IRP trace was transmitted via Bluetooth and displayed on a laptop computer positioned at the back of the operating theatre, behind the operating surgeon, with the screen facing away and visible only to the researcher recording the data.

Follow-up

Patients were followed up clinically until removal of the ureteric stent, typically at 2 weeks after surgery.

Statistical analysis

IRP traces were exported to Microsoft® Excel (Microsoft, Redmond, WA, USA). Baseline pressure traces and intraoperative pressure traces for the duration of RIRS, including calyceal exploration and laser lithotripsy, were analysed, with mean, maximum, and other IRP values reported reflecting this interval. Where a period of basket extraction of stone fragments had been employed, typically resulting in a sharp drop in IRP, the corresponding pressures were subtracted from the intraoperative pressure trace to avoid artificially reducing the mean pressure.

Numerical data were assessed for normality through visual inspection of histograms and Q–Q plots. The secondary outcome variance of IRP was found to be positively skewed, and

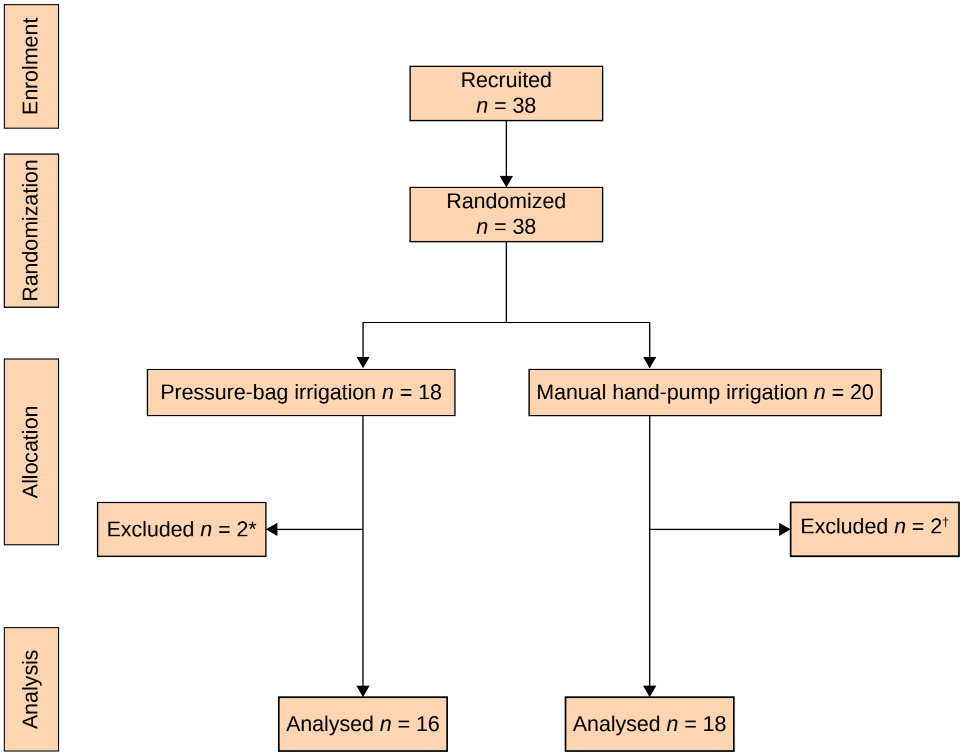

Fig. 1 Study flow chart

*Owing to early accidental laser damage of pressure wire (1), and intraoperative discovery of a ureteric stricture prohibiting ureteral access sheath passage (1). †Owing to pressure-wire migration into ureter (1) and intrarenal stones being smaller than anticipated and requiring basket extraction only (1).

transformed to normality using natural log transformation. Categorical variables were summarized as the number in each group and continuous variables as mean(s.d.). Differences in outcomes between HP and PB arms were examined by independent-samples Student's *t* tests, using pooled variance if equal group variances could be assumed under Levene's test, and Welch's *t* test where equal group variances could not be assumed. Difference in means (MD) with associated 95% confidence interval and Cohen's D effect size (d)[11] were computed for each outcome comparison, with effect sizes classified as large (d = 0.8), medium (d = 0.5) and small (d = 0.2). Pearson's correlation was used to examine the association between operator-perceived HP force and measured IRP. A sensitivity analysis of the results to the assumptions underpinning Student's *t* tests was undertaken by re-running the between-group comparisons using the non-parametric Mann–Whitney *U* test. All analyses were undertaken using two-tailed tests at the 5% level of significance. SPSS® Statistics for Windows® version 29.0. (IBM, Armonk, NY, USA) was used for statistical analyses.

Results

Participants

Thirty-eight patients were recruited and randomized from July to November 2023, and 34 were ultimately included in the analysis: 16 in the PB arm and 18 in the HP arm (Fig. 1). Exclusions from the PB arm were due to early accidental laser damage of pressure wire (1) and intraoperative discovery of a ureteric stricture prohibiting ureteral access sheath passage (1). Exclusions from the HP arm were due to pressure-wire migration into the ureter (1) and intrarenal stones being smaller than anticipated and requiring basket extraction only (1). Operating teams complied with the allocation in all instances. The study was stopped when target recruitment was reached. Per-protocol analysis was undertaken. Data collection was complete across all variables for the included patients.

Table 1 Preoperative variables for patients in each group

	Pressurized-bag irrigation (*n* = 16)	Manual hand-pump irrigation (*n* = 18)
Age (years), mean(s.d.)	58.25 (14.43)	55.71 (12.82)
Sex		
Male	7	12
Female	9	6
Stone size, maximum dimension (mm), mean(s.d.)	11.56 (5.78)	9.9 (3.54)
Pre-stented	1	2
Baseline IRP (mmHg), mean(s.d.)	13.51 (4.2)	15.56 (5.62)

IRP, intrarenal pressure.

Patient demographics and preoperative variables are presented in Table 1. Most patients (32 of 34) had an ASA fitness grade of I or II. One patient in each arm was taking a calcium-channel blocker; none was taking α-blockers. No patient had preoperative ureteric obstruction.

Outcomes

Procedural intrarenal pressure

Table 2 shows the results of statistical analysis of the primary and secondary outcomes. Compared with patients in the PB arm, those in the HP arm experienced significantly higher mean IRP (MD 24.13

Table 2 Study outcomes

	Pressurized-bag irrigation (*n* = 16)	Manual hand-pump irrigation (*n* = 18)	MD* §	Cohen's D effect size	*P*
Primary outcome					
Mean IRP (mmHg)	38.16 (16.84)	62.29 (27.45)	24.13 (7.97, 40.29)	1.05	0.005¶
Secondary outcomes					
Maximum peak IRP† (mmHg)	68.04 (24.16)	192.71 (106.23)	124.67 (70.76, 178.59)	1.58	< 0.001#
Natural log of variance IRP	4.60 (1.30)	6.23 (1.59)	1.64 (0.62, 2.66)	1.12	0.001¶
Operator-reported visualization‡	8.75 (0.58)	6.28 (1.27)	2.47 (1.79, 3.16)	2.45	< 0.001#
Procedure duration (min)	12.65 (8.04)	11.72 (6.68)	0.93 (4.22, 6.07)	0.13	0.716¶

Values are mean (s.d.), except *values in parentheses are 95% confidence intervals. †Mean of maximum peak pressures recorded for each trace. ‡Measured on 10-point scale (1, very poor; 10, perfect). §Difference in means (MD) between pressurized-bag and hand-pump irrigation. ¶t test with equal variances assumed, except #Welch's *t* test with variances not assumed. IRP, intrarenal pressure.

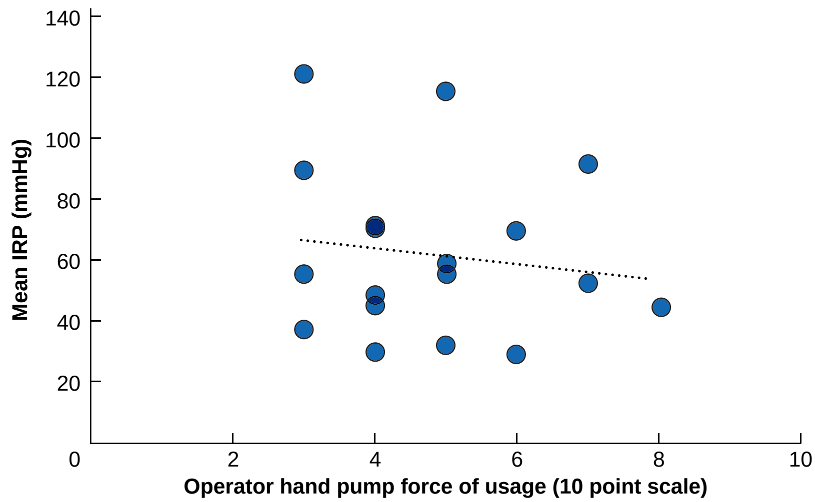

Fig. 2 Hand-pump force of usage *versus* intrarenal pressure

IRP, intrarenal pressure. Pearson *R* –0.15 (95% c.i. –0.57 to 0.35) ($P = 0.57$).

(95% c.i. 7.97 to 40.29) mmHg; $P = 0.005$) with a large effect size (d = 1.05) and a clinically meaningful difference. Patients in the HP arm also experienced significantly higher maximum IRP pressure peaks (MD 124.67 (70.76 to 178.59) mmHg; $P < 0.001$; d = 1.58) and greater variance in IRP during the procedure, as measured by the natural log transform (MD 1.64 (0.62 to 2.66); $P = 0.001$; d = 1.12) than those in the PB arm; effect sizes were large for both outcomes.

Operator-reported visualization

The primary operating surgeon, who performed laser lithotripsy, scored subjective satisfaction with clarity of procedural vision on a 10-point scale, from 1 (very poor) to 10 (perfect). Operator satisfaction with vision was significantly greater with PB compared with HP irrigation (MD 2.47 (1.79 to 3.16); $P < 0.001$), with a strong effect size (d = 2.45).

Sensitivity analyses

Sensitivity analyses using the non-parametric Mann–Whitney *U* test showed the statistical significance of the between-group differences to be robust to the statistical test used (*supplementary material*).

Hand-pump force of usage

One of three surgeons acted as a surgical assistant and operated the HP for all procedures. HP users were asked at procedure completion to rate overall HP usage, incorporating frequency and force, on a 10-point scale (1, minimal; 10, maximum). A score of 3–8 was chosen in all instances. *Figure 2* shows a scatterplot of mean IRP plotted against self-reported force-of-usage scores. The Pearson correlation coefficient of –0.15 (95% c.i. –0.57 to 0.35) was not statistically significant ($P = 0.570$). No clinically relevant differences were observed between the three HP users in overall IRP or strength of correlation between perceived usage force and recorded IRP.

Clinical outcomes and complications

Endoscopic stone clearance was achieved in all patients. One patient in the HP arm experienced intraoperative bleeding from the collecting system that obscured vision and required the procedure to be paused temporarily. The procedure was ultimately completed satisfactorily, with no appreciable change in serum haemoglobin level. One further patient in the HP group developed urosepsis requiring intravenous antibiotics (Clavien–Dindo grade II), and recovered well. No morbidity was observed in the PB cohort.

Discussion

Although there has been growing awareness of the potential for negative clinical sequelae from high pressure increases during RIRS, there has been a paucity of knowledge around the relationship between aspects of operative technique and IRP. This has meant that, despite aspirations to limit renal pelvic pressure during RIRS, urologists have had to make decisions relating to IRP based on assumptions, best-guess hypotheses, and scanty *ex vivo* evidence.

This study presents the first *in vivo* analysis of the impact of irrigation technique on IRP, and has a number of interesting findings. First, PB irrigation at 100 mmHg was associated with lower IRP than manual HP irrigation. This may counter popular belief. In a global practice study[8], the authors previously found that 88.3% of urologists were concerned about reducing IRP in their practice. When asked about strategies used in an endeavour to mitigate against high IRP, over one-third (177, 34%) stated they 'avoid[ed] pressure bag irrigation', whereas only 77 (15%) stated that they 'avoid manual irrigation devices'. This seems to imply a perception among the urological community that PB irrigation risks higher IRP than HP irrigation, and is congruent with findings of HP being the most common choice of RIRS irrigation in Europe[7] and globally[8]. This may be related to a feeling of enhanced user control with manual pump irrigation; 207 respondents (40%) in the former study stated that they 'use manual irrigation devices but with 'gentle' pressure only'. However, the findings of this study question how confidently such a statement can be made. It was discovered that surgeon perceptions of HP usage force correlated very poorly with the actual pressure transmitted to the renal pelvis. In two instances where the surgeon rated pump use as 3 of 10, mean IRP readings for the duration of the procedure were 90 and 120 mmHg. In one of these, a peak pressure of 330 mmHg was recorded within the collecting system, a level potentially exceeding the rupture threshold of a collecting system[12]. Conversely, a more moderate mean IRP of 44 mmHg was recorded in the context of a surgeon recording HP usage as 8 of 10. It has been shown, with other syringe devices, that human's perceptions of 'standard' force as a benchmark can be extremely variable[13]. Furthermore, it is hypothesized that individual-patient factors, such as collecting system volume, anatomy, and possibly compliance, may have a significant influence on the IRP experienced at a given level or force of HP usage.

This study has a number of limitations. Per-protocol analysis was used; although intention-to-treat analysis is often desirable in interventional RCTs, it did not seem appropriate here as patients were excluded after randomization on the basis of issues such as technical measurement failures, meaning that only very limited data, known to be inaccurate, were available. There were no instances of drop-out or cross-over between treatment groups based on clinical factors or surgeon choice. HP usage is user-dependent. To increase the generalizability of the present findings, three different experienced users of the HP were observed. There was a poor correlation between reported usage and IRP. Widely variable IRP resulting from HP usage has similarly been reported in the literature[14–16]. However, the authors acknowledge that the numbers are small for such comparisons, and that technique may vary among readers. Commercially available PB devices may vary, and may be set at pressures of 150 mmHg or higher[7,9]. It must be noted that, in this study, PB irrigation was maintained at, but not exceeding, 100 mmHg by circulating operating room staff, using a PB system with a clearly visible pressure dial. To avoid confounding variables, only patients undergoing RIRS with an 11/13-Fr ureteral access sheath were included. Correctly placed ureteral access sheaths have been shown to mitigate, to some extent, against raised IRP by providing consistent outflow drainage[14,15]. The authors therefore hypothesize that IRP would have been further raised in this study in the absence of a ureteral access sheath, but cannot conclude how it may have varied between study arms. It is also acknowledged that visual clarity is a subjective endpoint, albeit a highly relevant one. Surgeons recording their satisfaction with vision were not blinded to the irrigation technique, and this does allow some potential for bias. Pre-existing knowledge has identified an association between raised IRP and adverse clinical outcomes[2], and a previous study[9] noted a higher incidence of SIRS in patients undergoing HP irrigation. In the present study, use of 100-mmHg PB irrigation resulted in lower and more consistent procedural IRP traces than HP irrigation, and one case of urosepsis was noted in the HP arm. However, given the relatively low event rates, the study was not powered to identify differences in morbidity between the groups, and further research would be required to draw definitive conclusions in this regard.

This RCT, which included patients with urolithiasis who were undergoing RIRS with laser lithotripsy in the presence of an 11/13-Fr ureteral access sheath, demonstrated that manual HP irrigation resulted in significantly higher and more fluctuant IRP traces than 100-mmHg PB irrigation. Furthermore, surgeon-reported estimates of HP usage force were found to bear little correlation with the actual IRP recorded in the renal pelvis. Finally, surgeons reported significantly greater satisfaction with visual clarity during RIRS with use of 100-mmHg PB irrigation compared with manual HP irrigation.

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Author contributions

Stefanie Croghan (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Visualization, Writing—original draft), Sorcha O'Meara (Data curation, Investigation, Project administration, Resources), Eoghan Cunnane (Investigation, Methodology, Software, Visualization, Writing—review & editing), Michael Walsh (Conceptualization, Methodology, Supervision, Validation, Visualization, Writing—review & editing), Fergal O'Brien (Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing—review & editing), Rustom Manecksha (Conceptualization, Data curation, Investigation, Methodology, Project administration, Supervision, Validation, Writing—review & editing), Barry McGuire (Conceptualization, Data curation, Investigation, Methodology, Project administration, Supervision, Writing—review & editing), Kieran Breen (Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Visualization, Writing—review & editing), Niall Davis (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing—review

& editing), and Helen Purtill (Formal analysis, Writing—review & editing)

Disclosure

The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

Data availability

Study data are available upon reasonable request.

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